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ONLINE: CAS ONLINE, WPI, JAPIO, CLAIMS

(54) Gelatinous pastille containing nicotine

(57) The pastilles contain nicotine in an acacia gum or gelatine base and thus have a jelly-like consistency. The pastilles may be formed into bars or be cigarette shaped and contain nicotine dissolved in alcohol such a spirit or liqueur. Alternative flavourings such as aniseed or peppermint may be used and vitamins may also be included. The pastilles overcome the disposal problems and social unacceptability of chewing gums.

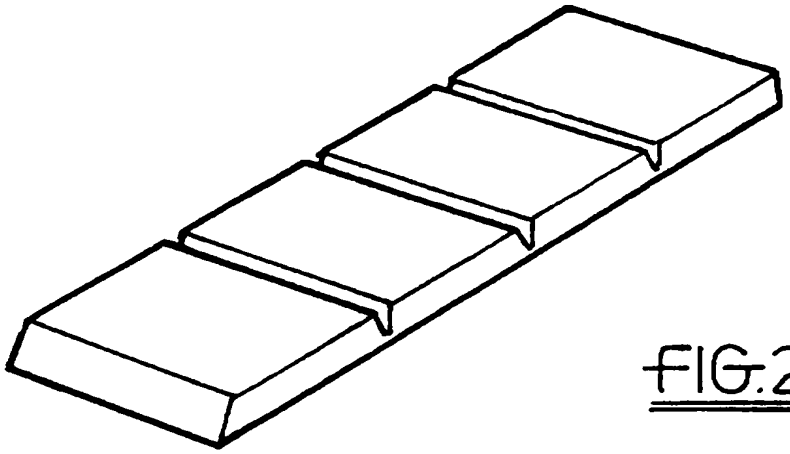

FIG.2

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed f rmal copy.

The claims wer filed later than the filing date within the period prescribed by Rule 25(1) of th Patents Rules 1995

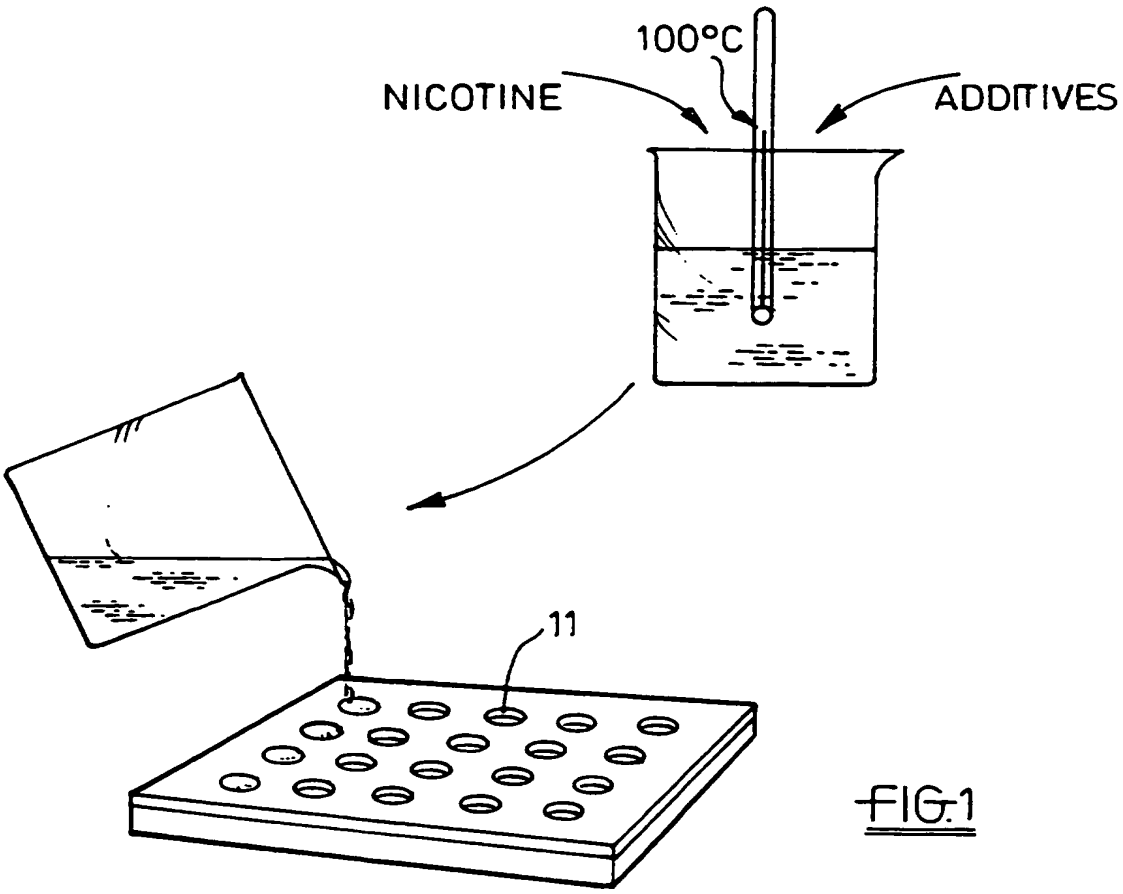

FIG.1

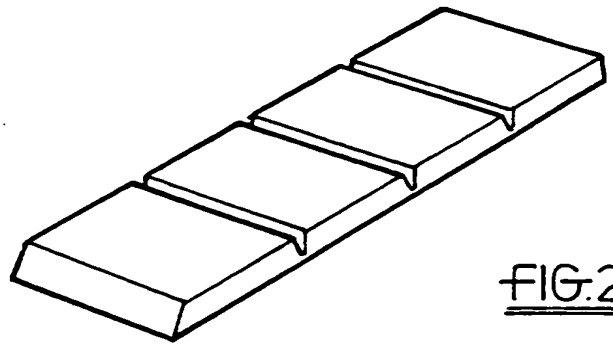

FIG.2

NICOTINE-CONTAINING PRODUCT

This invention relates to nicotine-containing products intended for use in therapy, as a smoking substitute or as an aid to quitting smoking.

Nicotine-containing products generally take the form of a chewing gum, though one product is available in the form of a small lozenge. The alternative nicotine replacement therapy product is a patch. Of the orally ingested products available, neither is totally satisfactory. The chewing gum has all the problems usually associated with chewing gum, including the disposal problem, and chewing is very often socially unacceptable. The small lozenge can be broken up by the action of chewing or even accidentally swallowed whole. The nicotine content is only effective if ingested by the buccal cavity tissues.

The present invention provides a new nicotine-containing product for oral ingestion which does not have the disadvantages of lozenges or chewing gum.

The invention comprises a nicotine-containing product for oral ingestion comprising a gelatinous pastille.

By "gelatinous" is meant "having the character or consistency of a jelly", more particularly of a chewable or suckable "wine gum" type of product which would be retained in the mouth whilst dissolving and not broken into fragments by chewing, generally starting off at too large a size to be readily swallowed.

The material from which the pastille is made may in fact be gelatine, or may comprise acadia gum with sorbitol, or may comprise other starches.

The nicotine may be present in the form of a nicotine salt or pure nicotine, which may be in solution e.g. in alcohol.

The pH may be controlled by a buffer to be at or substantially at normal mouth pH.

The product may be presented in a wrapping which seals in volatile nicotine.

The invention also comprises a method for making the product comprising adding nicotine to dissolved gelatine and allowing the gelatine (or other material) to dry in pastille moulds. The nicotine may be added after the gelatin , originally dissolv d in hot water, has cooled to below, say, 60°C, to avoid undue nicotine

loss due to evaporation. Pure nicotine is quite volatile. A final nicotine content of about 0.5 mg per pastille may be aimed at, and an excess of nicotine may be loaded into the dissolved gelatine to compensate for evaporation during drying. The pastilles may need to be dried in the mould for several days.

Traces of vitamins, particularly vitamin A, C and E, may be added as may dextrose and flavourings such as aniseed and/or peppermint.

A pastille may be of such size and contain as much nicotine as will correspond to the time taken to smoke a cigarette and the amount of nicotine absorbed by the tissues of the buccal cavity during such time. A pastille may typically be of at least wine gum size, but may be fashioned in a different shape, perhaps in the shape of an ingot, and perhaps breakable into smaller pieces for ease of accommodation in the mouth while providing the requisite dosage of nicotine over the appropriate time.

Nicotine-containing products and methods for making them according to the invention will now be described with reference to the accompanying drawings, in which :-

Figure 1 is a diagrammatic representation of the methods;

and Figure 2 is a view of a pastille made by a method as illustrated in Figure 1.

The drawings illustrate nicotine-containing product for oral ingestion comprising a gelatinous pastille 11.

The nicotine can be present in the form of a nicotine salt or complex such for example as a complex of ß-cyclodextrin (ß-CD) and nicotine.

Gelatine is dissolved in hot (boiling) water as a first step and the solution allowed to cool down to 60°C. To the partially cooled solution is added the nicotine, whether as salt or complex or in the form of pure nicotine in solution e.g. in alcohol. The resulting nicotine-containing gelatinous solution is poured into moulds 11 and allowed to dry, over a time interval extending to perhaps several days.

The moulds 11 are of such shape and size as to result in a pastille of wine gum size and consistency that will be dissolved over a time period measured in minutes when ing sted orally.

The nicotine content of the gelatinous solution will tend to evaporate during drying and an initial overprovision will normally be required in order to finish with a content of 0.5 mg per pastille in the dried product. The overprovision required can be readily determined by simple trial and error, and will depend upon the actual processing conditions, the temperatures used, the surface area of pastille exposed in the mould and so forth.

At the mixing stage any additives, fillers required can be added. Preferably trace quantities of one or more of vitamins A, C and E are included, as well as dextrose and flavourings.

For giving-up-smoking aids, mint and/or aniseed flavourings may be preferred, but a tobacco flavour could also be incorporated as could a spirit, liqueur or fortified wine or other alcoholic or non-alcoholic drink flavour could be incorporated.

The moulds 11 may mould disc-like pastilles, similar to wine gums, or shapes such as illustrated in Figure 2 can be made, namely a slim, elongated ingot shape with lines of weakness on which it can be broken into bite-siz d-pieces.

The pastilles will still be liable to some ongoing evaporation of their nicotine content, but this can be minimised by impervious packaging which will impart at least a reasonable shelf life.

CLAIMS

1. A nicotine-containing product for oral ingestion comprising a gelatinous pastille.

2. A product according to claim 1, comprising gelatine.

3. A product according to claim 1 or claim 2, comprising acacia gum.

4. A product according to claim 2 or claim 3, comprising sorbitol or other starches.

5. A product according to any one of claims 1 to 4, in which the nicotine is present in the form of pure nicotine.

6. A product according to claim 5, in which the nicotine is dissolved in alcohol.

7. A product according to claim 6, in which the alcohol is incorporated as a spirit, liqueur or fortified wine or other alcoholic drink.

8. A product according to any one of claims 1 to 7, in which the nicotine is incorporated as a nicotine salt or complex.

9. A product according to any one of claims 1 to 8, including a flavouring.

10. A product according to claim 9, in which the flavouring is a tobacco flavouring.

11. A product according to any one of claims 1 to 10, presented in a wrapping which seals in volatile nicotine.

12. A product according to any one of claims 1 to 11, presented in a size and of such consistency that it will be dissolved over a time period of at least one minute when ingested orally.

13. A product according to any one of claims 1 to 12, presented in a shape and size approximating to a cigarette.

14. A product according to claim 13, in which the shape is rod - or bar-like and has zones of weakness allowing it to be broken into smaller pieces for convenient oral ingestion.

15. A product according to any one of claims 1 to 14, containing a final nicotine content in the range between 0.1 and 1.0 mg per pastille.

16. A product according to any one of claims 1 to 15, containing traces of vitamins.

17. A product according to any one of claims 1 to 16, containing a sugar such as dextrose.

18. A method for making a nicotine containing product for oral ingestion comprising adding nicotine to liquid, dryable gelatinous material, filling pastille moulds with the liquid material and allowing it to dry in the moulds.

19. A method according to claim 18, in which the gelatinous material comprises dissolved gelatine.

20. A method according to claim 19, in which the gelatine is dissolved in hot water which is then allowed to cool to a level which avoids undue nicotine loss through evaporation.

21. A method according to claim 21, in which the gelatine solution is allowed to cool to below 60°C before adding the nicotine.

22. A method according to any one of claims 18 to 21, in which an excess of nicotine over that required in the final product to compensate for evaporation during drying.

The Patent Office

Application No: GB 9506386.3
Claims searched: 1 to 20

Examiner: Mr S.J.Pilling
Date of search: 22 July 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5B (BLE)

Int Cl (Ed.6): A61K 31/465, A61K 9/00, 9/20

Other: ONLINE: CAS ONLINE, WPI, JAPIO, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2142822 A	(SHAW) see page 2 lines 2 to 5	6,7
X:Y	WO 91/06288 A1	(DAM) see page 6 line 22 to page 7 line 28, page 16 lines 1 to 17, page 17 line 21 to page 18 line 19, page 19 lines 20 to 22 and the Examples.	X:1-5,8-20 Y:6,7

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.